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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,305	07/23/2003	Arnold P. Nerenberg	NERE-3692	.8392

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,305

Applicant(s)

NERENBERG, ARNOLD P.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-31 are presented for reconsideration on the merits.

Response to Amendment

The response filed January 4, 2005, has been received and entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran in view of Kato et al, McCarty, Riley et al, and Leslie et al., all cited on the PTO-892 Form and PTO-1449 Form for reasons set forth in the Office action of October 6, 2004.

Claims are drawn to a composition, comprising aspirin, magnesium and nattokinase and either niacin or nitroglycerine. Also Coenzyme Q, lipoic acid and amino acids are included in the composition.

Cochran discloses a composition comprising Coenzyme Q, niacin, amino acids, vitamins, lipoic acid, see column 17, lines 25-68 and column 18, lines 40-45. Also note column 20, all lines and Column 22, all lines.

Kato et al teach a composition comprising Nattokinase, see the abstract.

McCarty teaches a composition comprising magnesium, see the abstract.

Leslie et al teach a composition comprising nitroglycerine, see the abstract.

Riley et al teach a composition comprising aspirin, see the abstract.

The claims differ from Cochran in that various active ingredients are not disclosed.

It would have been obvious to one of ordinary skill in the art to combine the ingredients of the cited prior art to provide for a composition since each ingredient is well known in the art. To combine these ingredients of the cited prior art to provide for the composition is an obvious modification and one of skill would have expected successful results. To vary the amounts is clearly within the skill of an ordinary artisan. Thus, in the absence of persuasive evidence to the contrary the claims are prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed January 4, 2005, have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.

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1992). In this case, each of the cited references are cited based upon their whole teachings in combination with each other. Each reference teaches that the ingredients may be combined with each other as well as other ingredients. For example, Riley et al teach aspirin, niacin and magnesium can be combined note column 21, line 16, 21 and 41. Kato et al teach nattokinase is useful for treating and preventing lifestyle diseases of the body. Hence, with just these two references alone establish a prima facie case of because each reference discloses the nature of using these ingredients for treating and preventing disease or for whole health wellness, per se.

One of skill in the art would have been motivated to combine these ingredients because they would have recognized their beneficial use for treating disease as disclosed by the cited prior art. Riley et al clearly teach the combination of three of Applicants' required ingredients. Further, Applicants' own instant claims do not omit the combination of other ingredients of which they may include in their claimed composition. Likewise the same combination of ingredients disclosed by the cited prior art combination as a whole may be included also in Applicants' claimed composition. Each reference discloses that the ingredients are administered for treatment of a subject as Applicants may also be administered.

Leslie et al teach the combination of aspirin and nitroglycerine, note the abstract and column 10, lines 4-17. Cochran teaches the combination of niacin and magnesium as well as many of the other optional ingredients claimed by Applicants. McCarty teaches magnesium and aspirin, thus, one of skill would have been motivated to combine the ingredients of instant claim 1 based upon the cited prior art because each ingredient is recognized independently as well as a combination of them together by the cited prior art. There is a legal basis for and case law

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available wherein it has been shown that the combination of well known ingredients is obvious based upon their use together and individually in the prior art.

There is no showing on the record why the combination of these ingredients would provide an unexpected successful result for their use together. The amounts of each ingredient are merely optional and to select for optimum amounts of each ingredient for use together is clearly within the purview of an ordinary artisan. The cited prior art clearly demonstrates that optimum amounts are selected for based on the desired result. The desired result of the combined ingredients of the instant claims is the same as that of the cited prior art. The art clearly recognizes using ingredients which are naturally found in the body. One of skill would have expected successful results with their combination. Kato et al clearly teach, or at least suggest, Nattokinase in a composition, note column 3, Table 2, and lines 45-49.

Therefore, in the absence of persuasive and convincing evidence to the contrary the claims are deemed *prima facie* obvious to one of skill in the art for those reasons above and of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deborah K. Ware
March 18, 2005


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651